VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/14/08

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Richard Harvie, R. Ph.
Norman Ward, M.D.
Kathleen Boland, Pharm.D.
Cheryl Gibson, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Judy Jamieson, OVHA
Stacey Baker, OVHA
Lorraine Siciliano, OVHA
Nancy Miner, (MHP)
Jennifer Mullikin, OVHA

Guests:

Aaron Cowieson, Pfizer
Andrea Williams, Endo Pharmaceuticals
Carl Marchand, AstraZeneca
Carl Possidente, Pfizer
Christina Carmody, Endo
Daniel Martin, Elan
Doug Kenyon, MedImmune
Jenifer Buttle, Merck
Lee Taylor, Forest
Lynn Quaranta, Endo
Mark Cabatingan, Roche
Matt Badalucco, Merck
Mike DeOrsey, Abbott
Pamela DiPerrio, GSK
Renee Hagerty, Takeda
Scott Mosher, GSK
Shawn Harned, Forest
Tom Martin, Boehringer-Ingelheim
Ward Bennett, Centocor-OBI

Michael Scovner, M.D. Chair, called the meeting to order at 7:04 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The September 2008 meeting minutes were accepted as printed.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Drug Class Reviews: In order to keep meetings to a reasonable length, the Board will be trying to streamline the drug class review process with the use of consent agenda items and the posting of review documents on the web.
- Chronic Care Management Program: Health risk assessments have been found not to be useful in identifying patients and the process will be suspended in order to help with cost containment. The program will continue but patients will be identified in other manners.
- Specialty Pharmacy: Is moving forward and will be addressing some chronic care conditions. The program will offer support to patients as well as providing an anticipated 1.2 million dollars in savings.

4. **Medical Director Update:** Medical Director Absent

- Clinical Programs Update: See Administrative updates.

- Prescriber Comments: None to report.

5. **Follow-up items from Previous Meeting:**

- No Follow-up items

6. **Clinical Update: Drug Reviews:** *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Arcalyst® (rilonacept) Vial for Subcutaneous Injection: Not recommended for addition to the PDL. Due to the cost of therapy and the potential for off-label use, it is recommended that Arcalyst® require prior authorization with the criteria for approval being that the medication is prescribed for the treatment of Familial Cold Autoinflammatory Syndrome (FCAS) in patients ≥12 years of age or the medication is prescribed for the treatment of Muckle-Wells Syndrome (MWS) in patients ≥12 years of age. It was recommended additionally that the J-code for this drug be blocked in the medical benefit.

Public Comment: No public comment

Board Decision: The Board approved the recommendations as described but requested that prescribers be required to send in medical notes documenting the diagnosis.

- Fenoglide® (fenofibrate) Tablet: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being consistent with the other PA requiring medications in this category. That is, the patient is taking a statin concurrently and has had a documented side effect, allergy, or treatment failure with Tricor or the patient has had a documented side effect, allergy, or treatment failure to gemfibrozil and Tricor. It was also recommended that within this category that started and stabilized be removed as a criteria for approval for all non-preferred agents as patients should be able to switch to one of the preferred products.

Public Comment: No public comment

Board Decision: The Board unanimously approved the MHP recommendations as described. It was requested that the initial approval be for 3 months and then if the patient responds to therapy, further PAs may be granted for 1 year.

- Omnaris® (ciclesonide) Nasal Spray (abbreviated Nasal Corticosteroids class review): Not recommended for addition to the PDL. Due to the lack of comparative data and undetermined advantages of Omnaris® over other available intranasal corticosteroids, it is recommended that Omnaris® nasal spray require prior authorization with criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to at least two preferred nasal glucocorticoids. A quantity limit of one inhaler per month was recommended. It was also recommended that generic flunisolide 25 mcg/spray be moved to PA required with identical criteria. Monthly quantity limits were recommended for all products whether preferred or non-preferred.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations but requested that for approval of non-preferred products, the patient must have trials of all 3 preferred products.

- Renvela® (sevelamer carbonate) Tablets (abbreviated Phosphate Binders class review): Not recommended for addition to the PDL. Criterion for approval is recommended to be that the patient must have a documented side effect, allergy, or inadequate response to Renagel® (sevelamer hydrochloride). The length of authorization would be 1 year. It is recommended that Fosrenal®, Phoslo® and Renagel® continue to be available without PA.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations as described for Renvela® and the phosphate binder class.

- Voltaren® (diclofenac sodium 1%) Topical Gel): Not recommended for addition to the PDL. Due to the lack of comparative efficacy data and the availability of less costly treatment alternatives, it is recommended that prior authorization be required for Voltaren® gel (diclofenac sodium) with the criteria for approval being that the patient has a documented medical necessity for a transdermal formulation (ex. dysphagia, inability to take oral medications).

Public Comment: *Lynn Quaranta, Endo Pharmaceuticals* – Commented on the history of use of this product world wide and its suitability for single joint pain.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)* (Public comment prior to Board action)

Specialty Pharmacy

- Elaprase®:
  The criteria page was updated to explain that the drug must be obtained through OVHA's Specialty Pharmacy Vendor, ICORE Heathcare.

Public Comment: No public comment.

Board Decision: None needed.

- Growth Stimulating Agents:
  It was recommended that the category be more clearly outlined to define the preferred and non-preferred agents after PA. It was recommended that Omnitrope® move to non-preferred. All the growth hormones that have specialized indications will be shown on the non-preferred side of the table in a separate sub-section. The letters to prescribers and beneficiary families were shared with the Board. The combination order form/PA form and patient ID/prescriber ID form that encourages the use of preferred products was discussed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board expressed concern that all pharmacies be notified so that stock would not be ordered.

- Hemophilia Factors:
  This is not a managed category. There are not preferred and non-preferred products – all factor products are equally available. OVHA is working with the nurse clinicians of the Hemophilia Clinics who see Vermont Medicaid patients to coordinate the transition and develop an order form. All recommendations for standard of service for pharmacy providers of clotting factor concentrates for home use in patients with bleeding disorders as outlined by the Medical and Scientific Advisory Council of the National Hemophilia Foundation will be met.

Public Comment: No public comment.

Board Decision: None needed.

- Hepatitis C Medications:
  This category includes the oral ribavirins and injectable interferons. The clinical criteria manual page has been clarified to more clearly outline our preferred products. Letters to prescribers and beneficiaries were shared as well as the order form that emphasizes preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the clarified criteria and preferred (after PA) products.

- Multiple Sclerosis Injectables:
  The self injectable products will now be provided by Specialty Pharmacy (ICORE). Tysabri® is not included in this initiative as it is not self-injected. Letters for prescribers and beneficiaries as well as the order form were shared.

Public Comment: No public comment.

Board Decision: None needed.

- Synagis®:
  The American Academy of Pediatrics has not changed their criteria recommendations for Synagis® so no changes are recommended. Wilcox Home Infusion will serve as the Specialty Provider for Synagis® this year. The order form containing the PA criteria that has been updated for Wilcox Home Infusion was shared with the Board.

Public Comment: No public comment.

Board Decision: None needed.

Annual Review – No Changes Recommended

- Acne Drugs: Oral
- Acne Drugs: Topical – Anti-Infectives
- Acne Drugs: Topical - Retinoids
- Acne Drugs: Topical – Rosacea

No changes were recommended to the above four categories.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Alzheimer's: Cholinesterase Inhibitors/NMDA Receptor Antagonists

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anemia Medications: Hematopoietic/Erythropoietic Agents

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anticoagulants

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anti-Emetics: 5-HT3 receptor Antagonists

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above. A Board member asked that the Board revisit the need for quantity limits at a later date.

- Anti-Emetics: Other

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anti-Infectives: Macrolides

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anti-Infectives: Miscellaneous

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Anti-Infectives: Oxazolidinones

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Glucocorticoids: Topical

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Pulmonary: Antihistamines-1st Generation

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Pulmonary: Systemic Glucocorticoids

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Saliva Simulants

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Vitamins: Prenatal Vitamins

No changes were recommended in this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

8. New Drug Classes:

- No New Drug Classes

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Lidoderm® (lidocaine 5%) Transdermal Patch: The prior authorization program for Lidoderm® was implemented on June 1, 2008. A review of utilization data showed a decrease in the number of unique utilizers, paid claims and the amount paid during the 4 months following implementation despite current users being grandfathered. From March 1, 2008 to May 31, 2008 there was a monthly average of 170 unique utilizers (range 169-180), resulting in 521 paid claims costing $113,695.62. During the period from June 1, 2008 to September 30, 2008 following the prior authorization program implementation, there was a monthly average of 74 unique utilizers (range 67-92), resulting in 309 paid claims costing $73,233.24. There was a 36% decrease in the cost of paid claims for Lidoderm®. In addition, after reviewing 41 prior authorization requests and the evidence regarding the management of neuropathic pain, it has been concluded that the prior authorization criteria for Lidoderm® is appropriate. An informal review of subsequent claims post prior authorization denial did not show any concerning patterns of new drug use. No changes to the current Lidoderm® approval criteria are recommended at this time.

Public Comment: No public comment.

Board Decision: The Board agreed that approval criteria are appropriate.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 09/11/08 - 09/25/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Statin Drugs-no link with ALS: An FDA analysis provides new evidence that the use of statins does not increase incidence of amyotrophic lateral sclerosis (ALS), a neurodegenerative disease often referred to as "Lou Gehrig's Disease." The FDA analysis, undertaken after the agency received a higher than expected number of reports of ALS in patients on statins, is based on data from 41 long-term controlled clinical trials. The results showed no increased incidence of the disease in patients treated with a statin compared with placebo. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Epoetin alfa-more deaths in study when used to treat acute ischemic stroke: The FDA has been made aware of preliminary safety findings from a clinical trial conducted in Germany investigating the use of epoetin alfa to treat acute ischemic stroke. The clinical trial utilized doses of epoetin alfa that were considerably higher than the doses recommended for the treatment of anemia as described in the FDA-approved labeling for the product. Over a period of ninety days after the start of the trial, there were more deaths in the group of patients who received epoetin alfa compared to patients who received the placebo (16% versus 9%). No changes were recommended in criteria for epoetin alfa at this time. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above.

- Tarceva® - hepatic failure: OSI and Genentech notified healthcare professionals that cases of hepatic failure and hepatorenal syndrome, including fatalities, have been reported during use of Tarceva®, particularly in patients with baseline hepatic impairment. Patients with hepatic impairment receiving Tarceva® should be closely monitored during therapy. It was recommended that the alert be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Rituxan®-case of PML: Genentech informed healthcare professionals of revisions to prescribing information for Rituxan® regarding a case of progressive multifocal leukoencephalopathy (PML) leading to death in a patient with rheumatoid arthritis who received Rituxan® in a long-term safety extension clinical study. It was recommended that the communication be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed

- TNF blockers-opportunistic infections not recognized: The FDA notified healthcare professionals that pulmonary and disseminated histoplasmosis, coccidioidomycosis, blastomycosis and other opportunistic infections are not consistently recognized in patients taking tumor necrosis factor-α

blockers (TNF blockers). This has resulted in delays in appropriate treatment, sometimes resulting in death. This information will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed

- Spiriva® - increased risk for mortality and/or cardiovascular event: The FDA informed healthcare professionals that FDA has reviewed preliminary data from UPLIFT (Understanding the Potential Long-Term Impacts on Function with Tiotropium), a large, 4-year, placebo controlled clinical trial with Spiriva HandiHaler in approximately 6000 patients with chronic obstructive pulmonary disease. The preliminary results reported by Boehringer Ingelheim to the FDA showed that there was no increased risk of stroke with tiotropium bromide compared to placebo. Two recent publications reported increased risk for mortality and/or cardiovascular events in patients who received tiotropium or inhaled anticholinergics. Both studies examined cardiovascular outcomes. The FDA expects to receive the complete report for UPLIFT in November 2008. It was recommended that this communication be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed

13. Adjourn: Meeting adjourned at 9:04 p.m.

Next DUR Board Meeting
Wednesday, November 12, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.